

REMARKS

Claim 10 is currently pending in this application. Claim 11 has been added. Reexamination and reconsideration of the application is respectively requested.

The Examiner rejected claim 10 as being obvious over a primary reference (Jang) in view of five other secondary references (Hughes, Martin, Lahay, Byrnes and the European patent), totaling five separate rejections. In each of these five separate rejections, the Examiner still fails to identify the motivation or suggestion found in the references themselves or in the knowledge available to one of ordinary skill in the art, which is needed to establish a *prima facie* case of obviousness. In each rejection, the Examiner merely repeats the phrase that "it would have been obvious to one with ordinary skill in the art to use the teachings of [Hughes, Martin, Lahay, Byrnes, or the European reference] to modify the invention of Jang to create a catheter assembly with a retaining element that keeps the two wires in a spaced apart relationship proximal to the elongated catheter in order to hold and prevent the guide wires from slipping." No reasoning is given. Applicant continues to submit that there is no motivation or suggestion found in any of the references to combine the intravascular catheter of Jang with the device disclosed in any one of the five secondary references. Jang does not provide any suggestion that a retaining member is needed to separate guide wires proximal to the catheter, and none of the secondary references mention the ability to retain two separate guide wires proximal to a catheter. Neither Jang nor any of the secondary references mention or recognize the existence of the problem that is solved by

the present invention precluding a finding of obviousness with regard to the claimed solution thereto.

In the Response to Arguments section of the Office action, the Examiner contends that each of the secondary references all disclose a retaining element as claimed by the instant application, and that "structurally, the retaining elements of the aforementioned inventors are identical to the Applicant's retaining element as claims." The Examiner also states that "Applicant is merely reciting the function of his retaining element." Applicant is confused by the Examiner's remarks because claim 10 is a method claim, not an apparatus claim. Claim 10 recites a method of preparing a bifurcated vessel for an interventional procedure, wherein one of the steps recited is "providing a retaining element for retaining the tracking guide wire and the integrated guide wire in a spaced apart relationship proximal to the elongated catheter." As will be discussed separately in greater detail below, none of the prior art references disclose holding two guide wires in a spaced apart relationship proximal to a catheter.

Also, in this section of the Office action the Examiner contends that "it would have been obvious to one with ordinary skill in the art to take the retaining elements of any one of the prior art references and use it to hold the two guidewires apart from one another, since that is precisely what is disclosed as a teaching, motivation, and/or suggestion of the prior art." The Examiner still fails to identify any motivation or suggestion found in the references themselves or in the knowledge available to one of ordinary skill in the art to combine the references, which is needed to establish a *prima facie* case of obviousness. Applicant challenges the Examiner to point to any disclosure

in any of the cited references to show "what is disclosed as a teaching, motivation, and/or suggestion of the prior art" that makes combining Jang with any of the secondary references proper.

Claim 10 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Jang (U.S. Patent No. 5,462,530) in view of Hughes (U.S. Patent No. 268,407). The rejection is respectfully traversed.

Claim 10 recites a method that provides for a "retaining element for retaining the tracking guide wire and the integrated guide wire in a spaced apart relationship proximal to the elongated catheter." The retaining element retains two (2) separate wires, i.e., the tracking guide wire and the integrated guide wire. Neither Jang nor Hughes discloses a device for retaining two separate guide wires in a relative position as recited in claim 10. Hughes only discloses a block that holds a single rubber tube wrapped around the limb of patient. Therefore, even assuming *arguendo* that Hughes can be combined with Jang, the result will be a retainer for retaining a single rubber tube in a coiled position, which will not hold two separate guide wires and will not maintain the relative lateral and longitudinal relationship of two wires. The Examiner is using impermissible hindsight based on the present invention to find that these references will form the claimed invention. All the elements of claim 10 are not disclosed in Jang or Hughes, and therefore, claim 10 is allowable over the prior art.

Claim 10 has also been rejected under 35 U.S.C. §103(a) as being unpatentable over Jang (U.S. Patent No. 5,462,530) in view of Martin (U.S. Patent No. 5,366,444). This rejection is respectfully traversed.

As discussed above, claim 10 includes a limitation that the retaining element retains two separate guide wires, i.e., the tracking guide wire and the integrated guide wire. Neither Jang nor Martin discloses a device for retaining two separate guide wires. Martin discloses a guide wire advancement device that includes a coiled tube 24 which houses a single guide wire, and clips 26 and 28 that hold the coiled tube in place. Martin does not disclose a retaining element for retaining two guide wires in a spaced apart relationship, and there is no suggestion that the device disclosed in Martin is applicable for two wires. Further, the clips retain the coiled tube and not the single guide wire. Even further, the clips do not retain the single guide wire because the guide wire is free to move inside the coiled tube, and the clips can not maintain two separate guide wires in a spaced apart relationship as recited in claim 10. Therefore, even assuming *arguendo* that Martin can be combined with Jang, the result will be a retainer for retaining a coiled tube with a guide wire inside, which will not hold two separate guide wires themselves and will not maintain the relative lateral and longitudinal relationship of two wires. The Examiner is using impermissible hindsight based on the present invention to find that these references form the claimed invention. For these reasons claim 10 is patentable over Jang in view of Martin.

Examiner further rejected claim 10 under 35 U.S.C. §103(a) as being unpatentable over Jang (U.S. Patent No. 5,462,530) in view of Lahay (U.S. Patent No. 6,696,920). This rejection is also respectfully traversed.

Applicant respectfully submits that not all elements of claim 10 are taught or suggested by Jang and Lahay because neither discloses a retaining element for retaining the tracking guide wire and the integrated guide wire in a spaced apart relationship proximal to the elongated catheter. Lahay only discloses an organizing device including a block of semi-rigid foam, and not a retaining element for retaining two guide wires in a spaced apart relationship as recited in claim 10. Lahay further does not disclose a device that will maintain the two guide wires in both a lateral as well as a longitudinal relationship as the two wires are moved during the procedure. The Examiner is using impermissible hindsight based on the present invention to find that these references form the claimed invention. For all of these reasons, claim 10 is also patentable over Jang in view of Lahay.

Examiner has also rejection claim 10 under 35 U.S.C. §103(a) as being unpatentable over Jang (U.S. Patent No. 5,462,530) in view of Byrnes et al. (U.S. Patent No. 6,405,530). This rejection is respectfully traversed.

Not all elements of claim 10 are taught or suggested by Jang and Byrnes et al. because neither discloses a retaining element for retaining the tracking guide wire and the integrated guide wire (two separate wires) in a spaced apart relationship proximal to the elongated catheter. Byrnes et al. discloses a coiling clip for holding a protective tube in a spiral, and not a retaining member for holding two guide wires in a spaced apart relationship, and there is no suggestion that the device disclosed in Byrnes et al. is applicable to two wires. Further, the coiling clips retain the protective tube in a spiral and not the single guide wire. Even further, the coiling clips do not retain the single guide

wire because the guide wire is free to move inside the coiled tube, and the clips can not maintain two separate guide wires in a spaced apart relationship as recited in claim 10. Therefore, even assuming *arguendo* that Byrnes et al. can be combined with Jang, the result will be a retainer for retaining a coiled tube with a guide wire inside, which will not hold two separate guide wires themselves and will not maintain the relative lateral and longitudinal relationship of two wires. The Examiner is using impermissible hindsight based on the present invention to find that these references form the claimed invention. For all of these reasons, claim 10 is patentable over Jang in view of Byrnes et al.

Claim 10 has also been rejected under 35 U.S.C. §103(a) as being unpatentable over Jang (U.S. Patent No. 5,462,530) in view of EP 0 587 984 A1 ("the European reference"). This rejection is respectfully traversed.

Applicant respectfully submits that not all elements of claim 10 are taught or suggested by Jang and the European reference because neither discloses a retaining element for retaining the tracking guide wire and the integrated guide wire (two wires) in a spaced apart relationship proximal to the elongated catheter. The European reference discloses a guide wire advancement device that includes a coiled tube 11 which houses a single guide wire 13, and a clip 60 that holds the coiled tube in place. The European reference does not disclose a retaining element for retaining two separate guide wires in a spaced apart relationship, and there is no suggestion that the device disclosed in the European reference is applicable for two wires. Further, the clip retains the coiled tube in a spiral and not the single guide wire. Even further, the clip does not retain the single guide wire because the guide wire is free to move inside the coiled tube, and the clip can

not maintain two separate guide wires in a spaced apart relationship as recited in claim 10. Therefore, even assuming *arguendo* that the European reference can be combined with Jang, the result will be a retainer for retaining a coiled tube with a guide wire inside, which will not hold two separate guide wires themselves and will not maintain the relative lateral and longitudinal relationship of two wires. The Examiner is using impermissible hindsight based on the present invention to find that these references form the claimed invention. For these reasons claim 10 is patentable of Jang in view of the European reference.

New claim 11 is also patentable over the prior art because it depends from allowable claim 10, and includes the limitation that "the retaining element directly holds the tracking guide wire and the integrated guide wire." The cited prior art references do not disclose a device that directly holds two separate guide wires. For these reasons, claim 11 is also allowable.

CONCLUSION

In view of the foregoing, applicant respectfully submits that the pending claims are in condition for allowance. Reexamination and reconsideration of the application as amended are respectfully requested and allowance at an early date is solicited.

Respectfully submitted,

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